

Layout and/or size adjusted for ease of reading and printing.

## FRONT LABEL

A07801-3


**CONTRAINDICATION/WARNING:**  
Do not take if you are pregnant and do not become pregnant while taking this medicine because it can cause miscarriage or other serious complications. See accompanying information.

Store at or below 25°C (77°F) in a dry area. 819 501 000

60 Tablets **Rx only**  
NDC 0025-1451-60


**Cytotec<sup>®</sup>**  
misoprostol tablets  
**100 mcg**

Usual Adult Dosage: See accompanying literature.

**PHARMACIA** 

**Pharmacist:** Dispense in this unit-of-use, child-resistant container with Patient Leaflet.  
Manufactured for: G.D. Searle LLC  
A subsidiary of Pharmacia Corporation  
Chicago, IL 60680, USA  
By: Searle & Co., Ciguias, PR


**Pharmacist:** Pull down tab to expose Patient Leaflet and space for Rx label.



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## BASE LABEL



<p><b>PHARMACIA</b></p> <p><b>Nota: El texto español sigue al texto inglés.</b></p> <p><b>Cytotec®</b> misoprostol tablets</p> <p><b>PATIENT INFORMATION</b></p> <p>Revised: March 2002</p>	<p><b>CONTRAINDICATION/WARNING:</b> Do not take if you are pregnant and do not become pregnant while taking this medicine because it can cause miscarriage or other serious complications. See accompanying information.</p> <p><small>Store at or below 25°C (77°F), in a dry place. Excipients may contain lactose. © 2002 Pharmacia Corporation, Chicago, IL 60680, USA by: Searle &amp; Co., Caguas, PR</small></p>	<p>60 Tablets <span style="float: right;">Rx only</span> NDC 0025-1451-60</p> <p><b>Cytotec®</b> misoprostol tablets <b>100 mcg</b></p> <p>Take as directed by your physician.</p> <p><b>PHARMACIA</b> </p>
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**BASE GLUED PAGE**

<p>Esta hoja informativa no cubre todos los posibles efectos secundarios de Cytotec. Esta hoja informativa para el paciente no se refiere a todos los efectos secundarios de su medicina para la artritis/dolor. Si tiene alguna pregunta, llame a su médico. Manténgase fuera del alcance de los niños.</p> <p><small>Manufactured for: G.D. Searle LLC A subsidiary of Pharmacia Corporation Chicago, IL 60680, USA by: Pharmacia Limited Searle &amp; Co. Morpeth, England Caguas, PR</small></p> <p style="text-align: right;"><b>PHARMACIA</b></p>	<p>Read this leaflet before taking Cytotec® (misoprostol) and each time your prescription is renewed, because the leaflet may be changed.</p> <p>Cytotec (misoprostol) is being prescribed by your doctor to decrease the chance of getting stomach ulcers related to the arthritis/pain medication that you take.</p> <p>Do not take Cytotec to reduce the risk of NSAID induced ulcers if you are pregnant. Cytotec can</p>
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<p>cause abortion (sometimes incomplete which could lead to dangerous bleeding and require hospitalization and surgery), premature birth, or birth defects. It is also important to avoid pregnancy while taking this medication and for at least one month or through one menstrual cycle after you stop taking it. Cytotec has been reported to cause the uterus to rupture (tear) when given after the eighth week of pregnancy.</p>	<p>unos días, muchos pacientes pueden continuar tomando Cytotec. Si usted sigue teniendo dificultad prolongada (más de 8 días), o si tiene diarrea grave, calambres y/o náuseas, llame al médico.</p> <p>Tome Cytotec siguiendo las instrucciones de su médico solamente.</p> <p>No dé Cytotec a nadie más. Ha sido recetado para su padecimiento específico y puede no ser el tratamiento adecuado para otra persona. También pudiera ser peligroso si la otra persona quedara embarazada.</p>
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<p>Cytotec y avise inmediatamente al médico.</p> <p>En algunas personas, Cytotec puede causar diarrea, calambres abdominales y/o náuseas. En la mayoría de los casos, estos problemas se presentan durante las primeras semanas del tratamiento y desaparecen después de una semana. Usted puede disminuir al mínimo la posibilidad de diarrea si toma Cytotec con los alimentos.</p> <p>Como estos efectos secundarios generalmente son de leves a moderados y usualmente desaparecen en</p>	<p>Rupture (tearing) of the uterus can result in severe bleeding, hysterectomy, and/or maternal or fetal death.</p> <p>If you become pregnant during Cytotec therapy, stop taking Cytotec and contact your physician immediately. Remember that even if you are on a means of birth control it is still possible to become pregnant. Should this occur, stop taking Cytotec and contact your physician</p>
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immediately.

Cytotec may cause diarrhea, abdominal cramping, and/or nausea in some people. In most cases these problems develop during the first few weeks of therapy and stop after about a week. You can minimize possible diarrhea by making sure you take Cytotec with food.

Because these side effects are usually mild to

tomarlo. Se ha reportado que Cytotec puede causar la ruptura del útero (desgarre) si se administra después de la octava semana de embarazo. La ruptura (desgarre) del útero puede resultar en sangrados serios, intervención quirúrgica, y/o muerte materna o fetal.

Si usted queda embarazada durante el tratamiento con Cytotec, deje de tomarlo y avise inmediatamente al médico. Recuerde que si usted emplea algún medio anticonceptivo, existe la posibilidad de que quede embarazada. Si esto ocurriera, deje de tomar

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estomacales relacionadas con la medicina que usted toma para la artritis/dolor.

Evite tomar Cytotec (para reducir el riesgo de úlceras) si está encinta. Cytotec puede causarle un aborto (algunas veces incompleto cual podría resultar en sangres peligrosos, requiriendo hospitalización y cirugía), parto prematuro o malformaciones. También es importante evitar quedar encinta mientras esté tomando este medicamento y por lo menos un mes, o la duración de un ciclo menstrual, después de haber dejado de

moderate and usually go away in a matter of days, most patients can continue to take Cytotec. If you have prolonged difficulty (more than 8 days), or if you have severe diarrhea, cramping and/or nausea, call your doctor.

Take Cytotec only according to the directions given by your physician.

Do not give Cytotec to anyone else. It has been prescribed for your specific condition, may not

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be the correct treatment for another person, and would be dangerous if the other person were pregnant.

This information sheet does not cover all possible side effects of Cytotec. This patient information leaflet does not address the side effects of your arthritis/pain medication. See your doctor if you have questions.

Keep out of reach of children.

**Cytotec®**

misoprostol tablets

### INFORMACION PARA EL PACIENTE

Lea esta hoja informativa antes de tomar Cytotec® (misoprostol) y cada vez que renueve su receta porque pueden haber cambios.

Su médico le ha recetado Cytotec (misoprostol) para disminuir la posibilidad de adquirir úlceras

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